Impact of the Prescription Drug User Fee Act of 1992 on the Speed of New Drug Development

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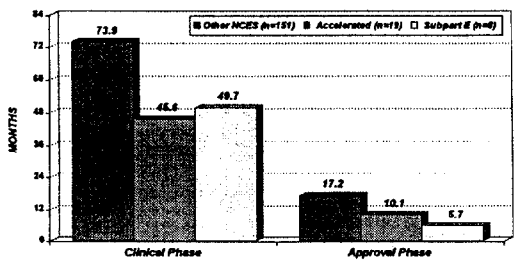
Regulatory Initiatives to Speed Availability of High Priority Drugs

- Subpart E Procedures (1988)
- Accelerated Approval Regulations (1993)
- Cancer Initiatives (1996)

Tufts CSDD

Development Times for Accelerated, Subpart E, and Other NCE Approvals, 1995-99



Source: Tufts CSDD Approved NCE Database, 2000

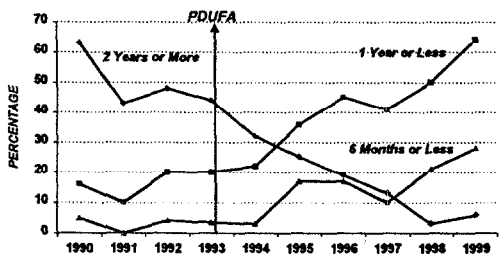
Tufts CSDD

Prescription Drug User Fee Act of 1992 Performance Goals

- 90% of Priority applications reviewed in 6 months
- 90% of Standard applications reviewed in 12 months
- Phased in over 5 years

Tufts CSDD

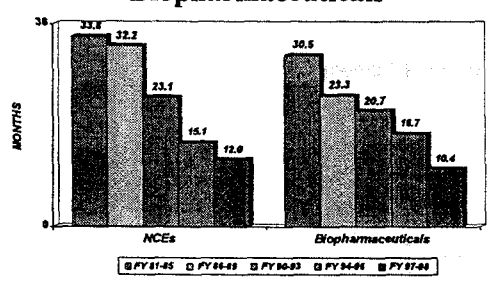
NCE Approvals in 2 or More Years, 1 Year or Less, and 6 Months or Less, 1990-1999



Source: Kaitin & DiMasi, Drug Inf J 2000;34:673-80

Tufts CSDD

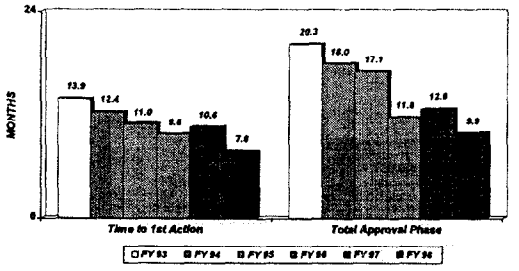
Approval Phases for NCEs and Biopharmaceuticals



Source: Tufts CSDD, 2000

Tufts CSDD

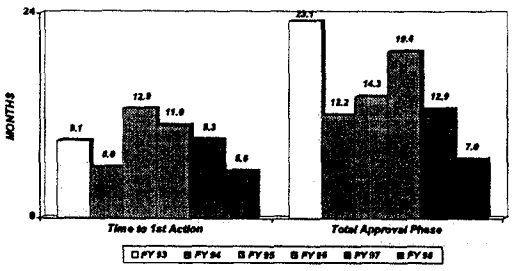
User Fee Review Phases for NCEs by FY Cohort



Source: Tufts CSDD, 2000

Tufts CSDD

User Fee Review Phases for Biopharmaceuticals by FY Cohort



Source: Tufts CSDD, 2000

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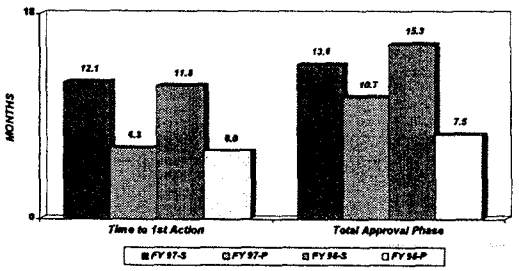
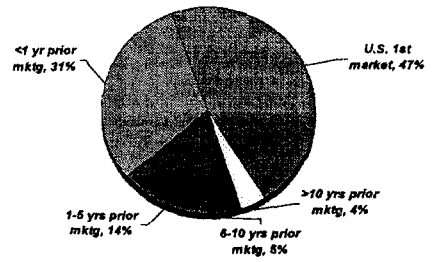
User Fee Review Phases for Standard and Priority NCEs, FYs 97-98



Source: Tufts CSDD, 2000

Tufts CSDD

Prior, Foreign Marketing of New Drugs Approved in the US, 1996-1998



Source: Kaitin & Healy, Drug Inf J 2000;34:1-14

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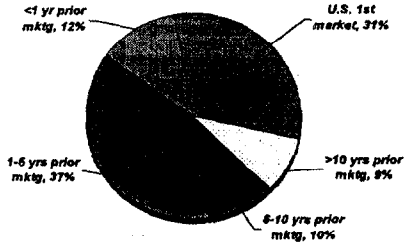
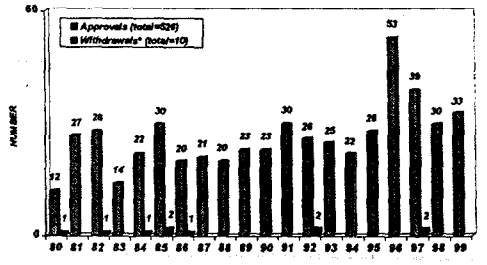
Prior, Foreign Marketing of New Drugs Approved in the US, 1991-1995



Source: Tufts CSDD Approved NCE Database, 1999

Tufts CSDD

New Drug Approvals and Withdrawals 1990-1999



* Withdrawals indicated by year of drug approval
Source: Tufts CSDD, 2000

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Conclusions

- PDUFA - most significant piece of drug legislation since 1962 Amendments
- Overwhelming success in speeding drug review process and changing the relationship between agency and sponsors
- Public ultimately benefits from faster access to important new drugs

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